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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,010	02/27/2006	Cynthia C. Bamdad	13150-70089US	8164

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,010	BAMDAD, CYNTHIA C.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,13,14 and 17* is/are pending in the application.

4a) Of the above claim(s) *57-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 13, 14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-6, 13, 14, 17, 27 and 57-62 are all the pending claims for this application.

2. Claims 2 and 3 were cancelled and Claims 1 and 4-6 were amended in the Response of 7/31/08.

3. Claims 57-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

4. Claims 1, 4-6, 13, 14 and 17 are all the pending claims under examination.

5. This action is FINAL.

Withdrawal of Objections

Specification

6. The objection to the specification for the improper use of the trademark Polyquick™ is withdrawn. The specification has been amended to capitalize the trademark.

Withdrawal of Rejections

Claim Rejections - 35 USC § 101

7. The rejection of Claims 1-6, 13, 14 and 17 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for an antibody found in nature is withdrawn.

Applicants' amendment of the claims to recite "isolated" antibody overcomes the rejection.

Claim Rejections - 35 USC § 112, second paragraph

8. The rejection of Claims 1-6, 13, 14 and 17 for the recitation "MGFR" in Claim 1 and PSMGFR in Claim 4 is withdrawn in view of the amendment of Claims 1 and 4 to recite the proper name for the intended antigen and antigen domain, respectively.

9. The rejection of Claims 5 and 6 for the recitation "sequence set forth in SEQ ID NO: 36 or a functional variant or fragment thereof" is withdrawn. The claims have been amended to clarify that the "fragment thereof" refers to the sequence of SEQ ID NO:36.

10. The rejection of Claims 5 and 6 because the claims recite broadening limitations for the PSMGFR of Claim 4 is withdrawn. The amendment of Claim 4 to depend from Claim 1 overcomes the rejection.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

11. The rejection of Claims 5 and 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants' allegations on p. 7 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "The present application exemplifies antibody production against a particular sequence, the PSMGFR as well as a variation of PSMGFR called var-PSMGF. Applicant has further provided a written description of this area, and also provided an antibody made against a variant PSMGFR in this region. Therefore, the present application provides written description sufficient to show possession of the antibodies against the claimed MGFR region."

Response to Arguments

The claims encompass a genus of antibodies produced against:

the sequence of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions; ***or***

the functional variant of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions; ***or***

the fragment of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions; ***and***

that also specifically bind the native MGFR protein.

The claims are not limited to which substitutions, insertions and deletions are permissive to the sequence of SEQ ID NO:36 that would allow the same antibody to specifically bind to both the modified SEQ ID NO:36 and the parent MGFR protein.

Antibody interaction occurs with epitopes defined by particular amino acid sequences. Consequently, it is not well known in the art at the time the invention was made or from the specification, the extent of amino acid modification that can be made to any epitope of the protein of SEQ ID NO:36 yet still retains antibody binding against the (or an) epitope on the MGFR protein as required by the claims.

The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions, fragments of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions or functional variants of SEQ ID NO:36 comprising up to 15 amino acid deletions or insertions at the N-terminus and up to 20 amino acid substitutions. Therefore, the identification of antibodies that bind to any one of the encompassed genus of peptides and which also specifically bind the MGFR protein is not supported by the specification.

Therefore, only an antibody generated against the isolated peptide of SEQ ID NO:7 (modified peptide of SEQ ID NO:36) and the antibody directed against the single variant sequence of SEQ ID NO:36, but not the full breadth of the claims meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. The rejection of Claims 1, 4-6, 13, 14 and 17 under 35 U.S.C. 102(e) as being anticipated by Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

Applicants' allegations on p. 8 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "The present application claims the benefit of priority to PCT/US2005/032821 (See the Declaration), which in turn claims priority to U.S. Application No. 09/996,069, which is the application number for the cited Bamdad '199 patent application publication. Therefore, Bamdad '199 is not citable against the present application."

Response to Arguments

The current filed Oath/ Declaration (2/27/06) does not list any of the above alleged priority information; the application transmittal letter of 2/27/06 does not list any of the above alleged priority information; the cross-reference to related applications in the original filed specification (2/27/06) does not list any of the above alleged priority information; and the filing receipt of 7/27/07 does not list any of the above alleged priority information. Still further, the sequence listing does not list any of the above

alleged priority information. No where in the file history is there documentation for the alleged priority claim. The rejection is maintained.

13. The rejection of Claims 1, 4-6, 13, and 14 under 35 U.S.C. 102(e) as being anticipated by Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of 1/31/08) is maintained.

Applicants' allegations on p. 8 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Kufe discloses MUC 1/ECD region, which roughly corresponds to PSMGFR sequence of the present invention. Kufe also discloses making an antibody to a fragment of the sequence. However, Kufe fails to understand the vast activity difference in effect between monovalent and bivalent MGFR specific antibody. Kufe fails to disclose the actual making of a monovalent antibody. Therefore, Kufe fails to provide an enabling disclosure of a monovalent antibody."

Response to Arguments

Kufe discloses on p. 2, line 16 an extracellular domain of MUC-1 protein comprising amino acid residues corresponding to SEQ ID NO:36 for the PSMGFR domain, antibodies against the PSMGFR domain in both monovalent and bivalent forms (pp. 10-14; p. 31), and pharmaceutical compositions (p. 26-29). Because the claims broadly recite any antibody binding to any region within the MGFR domain of the MUC1 protein inclusive of the PSMGFR domain, and Kufe teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, which corresponds to the

peptide sequence for the PSMGFR domain of Muc-1 shown on p. 2, line 16 of Kufe, the claims are considered to encompass an antibody binding to an unmodified sequence of SEQ ID NO:36 (native PSMGFR), where zero modifications are read into the range.

Kufe's disclosure for making monoclonal antibodies is explicit. Kufe disclosure for making monovalent antibodies is explicit. Applicants' argument that Kufe does not appreciate the difference(s) between monovalent and bivalent antibodies is irrelevant and gratuitous because none of the instant claims are drawn to a bivalent antibody. The rejection is maintained.

14. The rejection of Claims 1, 4-6, 13, and 14 under 35 U.S.C. 102(e) as being anticipated by Wreschner et al. (US 20050019324; published 1/27/05; filed 3/26/02; cited in the PTO 892 form of 1/31/08) is maintained.

Applicants' allegations on p. 9 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Wreschner discloses a monoclonal antibody (BOS7D10) against MUC1 that inhibits cell growth. However, the disclosed antibody appears to be a bi-valent antibody. Since Wreschner is silent as to the anti-cell proliferation effects of the monovalent antibody over bivalent antibody, the presently claimed monovalent antibody is distinguished over the bivalent antibody described in Wreschner."

Response to Arguments

Wreschner discloses an isolated antibody or fragment including monovalent and bivalent antibodies and fragments [0034; 0047], which specifically binds to an epitope in

the extracellular region of an isoform of MUC1 protein [0019] where the epitope is located in the 15 amino acid sequence that resides at the N-terminal portion of the 59 amino acid segment which is located directly N-terminal to the transmembrane domain of the MUC1/Y, MUC1/X and MUC1/REP proteins [0044], a pharmaceutical composition comprising the antibody [0056]. Because the claims broadly recite any antibody binding to any region within an MGFR domain of a MUC1 protein inclusive of the PSMGFR domain and the specification defines these domains as extracellular domains, and Kufe teach such antibodies, the claims are anticipated by the prior art. Because Claims 5 and 6 recite comprising language of "up to X" modifications to the sequence of SEQ ID NO:36, which corresponds to the peptide sequence for the extracellular domain of Muc-1 described in Wreschner, the claims are considered to encompass an antibody binding to an unmodified sequence for the extracellular (SEQ ID NO:36 (native PSMGFR)), where zero modifications are read into the range.

Wreschner's disclosure for making monoclonal antibodies is explicit. Wreschner's disclosure for making monovalent antibodies is explicit. Applicants' argument that Wreschner does not appreciate the difference(s) between monovalent and bivalent antibodies is irrelevant and gratuitous because none of the instant claims are drawn to a bivalent antibody. The rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The rejection of Claims 1 and 17 under 35 U.S.C. 103(a) as being unpatentable over Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of of 1/31/08) in view of Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

Applicants' allegations on p. 9 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Since Bamdad '199 is a priority application and therefore cannot be cited against the present application, this rejection is fails to be applicable to the present application."

Response to Arguments

See the examiner's comments under section 12 above as they apply here to the Bamdad reference. The rejection is maintained.

Conclusion

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643